Exhibit B

IN THE UNITED STATES BANKRUPTCY COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
(CHARLESTON DIVISION)

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	MASTER FILE NO. 2:12-MD-02327 MDL NO. 2327
THIS DOCUMENT RELATES TO ALL WAVE 8 AND SUBSEQUENT WAVE CASES AND PLAINTIFFS	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

Deposition of MARK ELLERKMANN, M.D.
Towson, Maryland
Friday, October 12, 2018
1:05 p.m.

Reported by: Linda M. Bahur, RPR

Deposition of MARK ELLERKMANN, M.D., held at:

SHERATON BALTIMORE NORTH HOTEL

903 Dulaney Valley Road

Towson, MD 21204

Pursuant to agreement, before Linda M. Bahur, a Notary in and for the State of Maryland.

A P P E A R A N C E S

ON BEHALF OF THE PLAINTIFF:

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EXAMINATION

PLAINTIFF EXHIBITS

(Attached to the transcript)

DEFENSE EXHIBITS

(Exhibit No. 1 retained by Mr. Snell)

P R O C E E D I N G S

(Plaintiff Exhibit Nos. 1-4 were marked for identification.)

Whereupon --

MARK ELLERKMANN, M.D.

being first duly sworn, as hereinafter certified, testifies as follows:

EXAMINATION BY MR. FAES:

Q Good afternoon, Dr. Ellerkmann. My name is Andrew Faes and I represent various plaintiffs in this litigation, and I'm here today to take your deposition regarding the Prolift case. Do you understand that?

A Yes, I do.

Q And you understand that you're under oath and you're sworn to tell the truth; right?

A Yes.

Q And if for any reason during the course of the day I ask you a question that doesn't make sense to you, just let me know and I'll try to rephrase the question. All right?

A I will.

Q First of all, I've premarked some

occasions?

A No, I wouldn't say that's accurate. Not less than five occasions, but less than 5 percent of the time.

Q Okay. Have you ever tracked a complication rate for the Prolift based on your personal use in your office?

A So I keep a database of my surgery, every surgery I've done even as a fellow. Not as a resident but as a fellow. I did my training here. And of that database, I kept a complication rate and still do.

Q And I don't see anywhere in your expert report where you say that you intend to state an opinion as to what your complication rate is with the Prolift®. Is that an opinion that you intend to offer in this case?

MR. SNELL: I'm going to object to the characterization. Go ahead.

A I can offer an opinion regarding my complication rate with respect to Prolift and that was that it was extremely low.

Q So extremely low. Can you put a numerator on that or a denominator or a

percentage?

A I can put a general percentage on that. It was probably less than 5 percent.

Q And that's all complications, not just erosion?

A It depends on what complication if we look at the no classification. You know, if we're talking about Class 1 complications, maybe higher. Urinary tract infections, something like that. But if we're talking about specifically mesh exposure, mesh erosion, less than 5 percent.

Q But as you sit here today, you can't give me, say, a denominator of the total number of cases of Prolift or the numerator of the total number of cases of Prolift?

MR. SNELL: Object to form. Go ahead.

Q Complications?

MR. SNELL: Object. Form.

A No. My overall complication rate with respect to Prolift, less than 5 percent.

Q And would you agree with me that that, since you can't give me the numerator or the denominator as you sit here today, that that 5 percent isn't based on any formal analysis that

think you called it a Class 1 complication, is that just Prolift/Gynemesh and Prolift+M or is that all of your pelvic organ prolapse meshes?

A I would say that that 5 percent, less than 5 percent erosion rate would apply to all transvaginal mesh that I've used in the last 15 years.

Q And have you ever broken it down between the Prolift and the Gynemesh PS and other vaginal --

A Not specifically.

MR. SNELL: Objection. Assumes with regard to Gynemesh PS being different than Prolift.

MR. FAES: Is it really your position, Counsel, that the Gynemesh PS is not different than the Prolift kit?

MR. SNELL: Actually, yes, it is. You know it's the same thing. It's the only thing left in the body. It's the only thing left in the body, period. They are the same. Unless you're going to take the position that it is not Gynemesh PS in the Prolift kit.

MR. FAES: Let's us not argue about it.

particular. No.

Q Okay.

A I may have glanced at them. Some of these articles that are listed here are articles I am familiar with because either my fellows wrote them or co-workers or colleagues. So that doesn't mean I read them back to back. I'm familiar. I spent my last 20, 25 years reading the literature, so that's how I spend a lot of my evenings.

Q So if I understood you correctly, you're not sure if you reviewed Piet Hinoul or Marty Wiseberg's deposition testimony?

A Yes. I'm not sure I've reviewed those in particular now.

Q Are there other materials that are listed in your reliance list that you haven't reviewed?

A I would say that most of these I have reviewed. Either read in their entirety or reviewed.

Q Most but not all?

A Right. So some of the depositions you said O'Toole. What page is that on?

Q It's the second-to-last.

Q Okay.
A But aside from that, no.
Q And with any of these doctors, did you have any kind of conversation about the amount or the amount of income you could expect if you became a consultant?
A No.
Q Would you agree with me that you've never written a peer-reviewed journal article specifically on the Prolift device?
A I would agree.
Q Are you doing any current research at all right now?
A I'm not doing any clinical trials right now. The last clinical trial I was involved with was a 522 study with Astora, anterior Elevate. You guys know how to spell it better than I do. I think it's S-T-O-R-A.
Q It's A-S-T-O-R-A.
A Yeah. I stand corrected. 522.
Q And that's the Embrace trial listed on your CV under recent clinical research; right?
A Correct.
Q And that study was actually terminated

because the product was no longer available; right?

A Yes.

Q And do you have any plans to publish or write up any of the research from that particular trial?

A No.

Q Okay. Would you agree with me that you're not a -- strike that.

Would you agree with me that you're not an expert in chemical engineering?

MR. SNELL: Object to form.

A No, I would not agree with that.

Q Okay. What experience do you have in chemical engineering?

A Well, I have years of working with polypropylene mesh in clinical settings. I know what material, how it reacts. I know how I found it to handle when I'm using it. I've been involved in various industry-sponsored meetings as a thought leader in the field, sharing ideas with colleagues about polypropylene mesh.

Q But you'd agree with me that you don't hold any kind of degrees or certifications in

chemical engineering; correct?

A I do. I would agree with you that I don't. Yes, I don't. I don't have a Ph.D in chemical engineering or any other specific degree, but I do have a lot of experience with polypropylene mesh.

Q Have you ever had any formal training in chemical engineering?

A Other than my classes in biochemistry as an undergraduate and medical student, I've not had any other formalized training. No.

Q And the classes you took as an undergrad, those weren't in chemical engineering specifically, were they?

MR. SNELL: Object. Form.

A They were in biochemistry.

Q Okay. And would you agree with me that -- do you hold yourself out -- strike that. Let me start over.

Do you hold yourself out as an expert in polymer chemistry?

A I'm an expert in polymer chemistry insofar as it relates to the use of polypropylene mesh in reconstructive pelvic surgery.

Q But you'd agree with me that you don't have any degree or certification specifically in polymer chemistry; right?

A No, I do not have degrees.

Q And have you had any formal education or training specifically in polymer chemistry?

A Other than seminars that I've attended and industry-sponsored, lack of a better term, think tanks regarding the use of polypropylene mesh in reconstructive pelvic surgery.

Q What seminars have you taken where polymer chemistry was discussed?

A Not specifically polymer chemistry but specifically looking at different types of polypropylene mesh -- that's one Type 2 mesh, Marlex mesh -- in their use of pelvic organ prolapse. As a pelvic surgeon, I have a lot of experience in different synthetic and biological grafts.

MR. FAES: Can you read just the first sentence of that answer back, because I'm not sure if I heard it right.

(The last question was read into the record.)

Q Would you agree with me that you've never done bench research on polypropylene?

A What do you define as bench research?

Q Well, let me back up and ask you a different question.

Do you know what bench research is in regards to medical device testing?

A Well, I think bench research, what it connotes to me is you're sitting in a lab and you have different machines, that you're looking at tensile strength and elasticity and porosity and looking at chemical compositions for specific meshes. I mean, that's what it connotes to me.

Q So using that definition of bench research, have you ever done any bench research on polypropylene?

A Using the specific definition I just gave you, sitting in a lab working with testing machines and so forth, the answer would be no.

Q Have you ever done any lab research on polypropylene?

A I have worked in cadaver labs.

Q Have you ever done any type of pathological analysis on explanted polypropylene

industry standards?

MR. SNELL: Object to form.

A I thought I just answered your question. And I think industry standards require medical device manufacturers to list potential complications or risks of their device without mandating that every potential complication of the device be noted, because many potential complications are within the common knowledge of the implanting surgeon.

Q And where does that standard come from? Where are you coming up with that standard?

A Well, that's just standard as far as I've been taught.

Q And who taught you that standard?

A I don't know. Somewhere along the last 25 years that's what I understood that to be.

Q But as you sit here today, you can't point to any treatise or document that states that that's the standard?

A I can't specifically reference you one, no. There is, indeed.

Q Okay. Would you agree that a medical device manufacturer should include a warning in

that statement.

Q Okay. So you don't think that that's the standard to be followed?

MR. SNELL: Objection. He's told you that three times.

Q Is that correct, you don't believe that is the appropriate standard to follow with a --

A That is correct.

MR. SNELL: Objection. Asked and answered.

Q -- medical device?

Have you ever reviewed any of the FDA's guidance for labeling in a medical device?

A I may have at some point.

Q Have you ever reviewed the FDA's Blue Book memo?

A I can't recall.

Q Do you believe that a medical device manufacturer like Ethicon should follow the FDA's guidance when deciding what warnings to put in their IFU?

MR. SNELL: Objection. Go ahead.

A I would think they would follow the FDA recommendations. Yes.

Q Do you know what departments of a medical device company are involved in creating the warnings for an IFU?

A What departments specifically?

Q Yes.

A No.

Q Have you ever read any testimony from any Ethicon employees regarding Ethicon's position on what needs to be in the IFU for the Prolift?

A So internal communications?

Q No. I'm talking about sworn testimony under oath.

A No.

Q Do you know what the FDA's requirements are regarding warnings for medical devices?

MR. SNELL: Object to form to the extent it has been asked and answered.

A Yes, I think I answered that already, Counsel. To the best of my knowledge, the FDA requires that a medical device company note potential serious risks of their device and serious complications while also acknowledging that the IFU is not a comprehensive document listing every potential risk or complication. I

think I've stated that a few times now.

Q Sorry. Are you done? I didn't mean to interrupt you.

A No.

Q Have you ever drafted the IFU for a medical device?

A No, I have not.

Q Have you ever worked on warnings for a medical device?

A No, I have not.

Q Have you ever worked on warnings for a prescription drug?

A No, I haven't, but may I go back to your answer just previously? Because something came to my mind.

Q Sure.

A I am actually on a board of advisors for a development that's currently R&D. We've just actually received an N.I.H. grant for a new type of pessary -- pessary, P-A-S-S-A-R-Y [sic] -- working with colleagues at Dartmouth-Hitchcock in Hanover, New Hampshire.

So to that end, I have counseled and provided Counsel regarding warnings for pessary

use.

Q Would you agree with me that you've never worked on the warnings for a polypropylene mesh device?

MR. SNELL: Object to form.

A Other than providing feedback at various summits and advisory meetings during my time as a preceptor with Gynecare or AMS for that matter.

Q So you actually provided feedback at seminars for Ethicon and Johnson & Johnson regarding warnings that were in the IFU for their polypropylene mesh devices?

A I would state it more different. I would state is differently, Counsel. I would say at various workshops and industry-sponsored summits, be they in Minnesota or in New Jersey, round table discussions that we had, we shared information with one another about our clinical experience, and I suspect that that information was tabulated and looked at and ultimately played a role in formulation of IFUs.

Q So during your time consulting for Ethicon specifically, did anyone at Ethicon ever

ask you what warnings they thought should be in the IFU for one of their polypropylene medical devices, whether orally or written?

MR. SNELL: Objection. Can you read that question back?

(The last question was read into the record.)

MR. SNELL: Are you asking did someone at Ethicon ask him what warnings that Ethicon, they thought?

MR. FAES: So let me see --

MR. SNELL: I don't know if you meant that.

MR. FAES: Let me see I can reask it.

MR. SNELL: I think I know what you're trying to ask but the question was really --

BY MR. FAES:

Q During your time consulting for Ethicon and Johnson & Johnson, did anyone at Ethicon ever ask you your opinion regarding what warnings you thought should be in a polypropylene mesh device?

A Not that I'm aware of specifically.

Q Would you agree with me that you never worked on warnings for a Class 3 medical device?

A I would agree. I mean, I think we all know that these devices were elevated to a Class 3 device at one point. But at that point in time, no, I never worked directly with that.

Q Would you agree with me that physicians should be made aware of all the significant safety risks associated with the Prolift in the IFU?

MR. SNELL: Objection. Asked and answered.

A Yes. I've answered that. I would disagree with that, Counsel. I think that the IFU is intended as a general guideline. Pelvic surgeons are made aware of risks of pelvic surgery when they're resident doctors when they do their first episiotomy. They know that can result in dyspareunia.

I mean, we all have a fund of knowledge of knowing complications of surgery whether we're using mesh or native tissue.

Q So if a corporate witness for Ethicon and Johnson & Johnson testified that that was the standard that Ethicon and Johnson & Johnson should follow, you would disagree with that?

A Yes, I would.

Q Have you ever been involved with the -- strike that.

Have you ever been involved with the design of a Class 3 medical device?

A Well, I mean insofar that transvaginal mesh was upgraded to Class 3. But prior to its being upgraded, I was involved with, as I said here, with development of transvaginal mesh.

Q You've never designed personally a polypropylene medical device; right?

A So have I sat down and actually drew sketches of it and submitted that to other engineers to consider? No. Have I participated in workshops in which experts in our field sat around together and talked about ideal properties of polypropylene mesh or mesh or biological materials, or for that matter, xenografts for use in pelvic floor reconstruction? Yes, I have.

Q You don't have any patents on any medical devices; correct?

A No, I do not.

Q Do you know what the standard is that a manufacturer must follow in designing mesh products?

A I don't know.

Q Okay. If the indications for the Gynemesh PS currently indicate that it's for abdominal use only, would you agree with me that implanting it vaginally would be an off label use transvaginally?

MR. SNELL: Objection.

A I don't agree with that statement because we have used Gynemesh PS transvaginally with good clinical outcomes. So it being off label use, I don't know if it would be or not, to tell you the truth.

Q Have you -- in forming your opinions in this case, did you ever review the design history file for the Prolift?

A I may have at some point.

Q Is it on your reliance list?

A I don't know if I have reviewed that at some point.

Q Do you recall any of what's in the design history file, if you reviewed it?

A I don't.

Q Did the contents of the design history file influence any of the decisions that you

formed in this case?

A It may have. Yes.

Q In what way?

A Well, I don't know because it's been a while since I glanced at that. I think if I read it, it may have influenced some point if I referenced it in my report.

Q Do you know what employees from Ethicon were involved in the design of the Prolift device?

A Which, no. I don't know specifically which employee, so.

Q So do you know who the chief engineer of the Prolift project was?

A I can't recall his name.

Q But it's fair to say that you've never reviewed any testimony that he's offered because you haven't reviewed testimony from any Ethicon employees; correct?

A That's correct.

Q Do you know what a failure modes and effects analysis is?

A Not specifically. No.

Q So it's fair to say, then, that you don't know what the purpose of failure modes and

effects analysis is?

A I can speculate but I don't know specifically. No.

Q Did you review any of the failure modes and effects analysis in this case?

A No.

Q Do you have any understanding of how the failure modes and effects analysis fits into the warnings for the device during the design process?

MR. SNELL: Objection. Foundation.

A Not specifically. No.

Q Do you know what a DDSA is?

A No.

Q Have you reviewed any of the DDSAs for the Prolift or Gynemesh PS in this case?

MR. SNELL: Object.

A No. Since I don't know what DDSA is in reference to, I wouldn't know if I reviewed it or not.

Q Have you ever reviewed any of Ethicon's standing operating procedures related to design?

A I may have at some point.

Q Did any of those affect any of the

opinions that you intend to offer in this case?

A They may.

Q How?

A Well, if I need to refresh my memory. But as we sit right here, they're not influencing any of my opinions because I'm not familiar with them.

Q Would you agree that Ethicon didn't design the mesh arms of the Prolift to rope and curl?

A That's a double negative. So did they design them to rope and curl?

Q Yes.

A They didn't design them to rope and curl. No.

Q Do you believe that the mesh arms of the Prolift can rope and curl?

A I don't know if they can rope and curl. I don't think so.

Q So you've never seen any photos of Prolift mesh arms roping and curling?

A I've seen photographs of explanted mesh and explanted Prolift, but not specifically with roping and curling.

complications they want to list in their IFU. That's not for me to decide.

What I'm saying for the record, once again, is that I don't believe that contraction of tissue and scarring of tissue is related to the polypropylene mesh.

Q So you believe that Ethicon can choose to put whatever warnings they want in their IFU?

A There are guidelines for what warnings they need -- we've been through this before -- that they, they need to or they are mandated to put in their IFU, and I am not knowledgeable of those specific guidelines.

Q Earlier you stated it was their prerogative. Would you agree that that's their prerogative to put additional warnings that may not necessarily be required in the IFU if they choose to do so?

MR. SNELL: Objection. Misstates.

A Ethicon works with the FDA and the FDA will require companies to list things in the IFU. The process by which that takes place, I can't specifically sit here and tell you now.

Q Would you agree with me that if they

want to, a company can list more warnings in their IFU than is required by law if they choose? Or do you know?

MR. SNELL: Objection. Foundation, legal conclusion, and way overbroad.

A I don't know.

Q Okay. Doctor, are you a member of ACOG?

A I am.

Q Do you agree with that -- strike that.

Do you agree that polypropylene mesh augmentation of anterior vaginal wall prolapse is associated with a higher rate of complications compared with native tissue repair?

A No, I do not.

Q So you disagree with that statement?

A I disagree with that statement.

Q And are you aware that that's a statement that ACOG has made in their most recent treatment guidelines issued in April of 2017?

A No, I'm not aware of that.

Q Have you reviewed ACOG's treatment guidelines for the treatment of pelvic organ prolapse?

treating pelvic organ prolapse?

A Yes, it would have.

Q Would that presentation have included your analysis and knowledge as to the design and the utility, if any, of such a device?

MR. FAES: Objection.

A Yes.

Q You told Plaintiff's counsel you also have experience analyzing the design of devices in cadaver labs?

A Yes.

Q Number 25, for example, lists a cadaver lab you did on Prolift and other devices. Do you see that?

A I do. It was here in Baltimore.

Q Did you do other cadaver labs on Ethicon devices where you analyzed the design of the device and the safety in places other than Baltimore?

MR. FAES: Objection.

A Yes, I did.

Q You were asked about the materials list that my firm put together and I believe you testified you did not read the two company witness

depositions that we put on that. Is that correct or wrong?

A That's correct.

Q Okay. Did you review, though, the company documents that we sent to you?

MR. FAES: Objection.

A I reviewed as much as I could, yes, of those documents.

Q Had you been reviewing company documents and materials pertinent to the Prolift actually even before becoming an expert in this litigation?

MR. FAES: Objection.

A I reviewed documents in the past from Ethicon as a preceptor and at our summit meetings. Yes.

Q And did you bring today response to plaintiff's deposition notice that was marked as Exhibit No. 1 the materials that you've considered and relied upon?

A I did. Yes.

Q Can you describe that for the court reporter, please, what you brought.

A So I have brought copies, both hard

copy and a flash drive containing all the literature that I had been able to review in preparation for my expert report and for this deposition.

Q Does that also include company documents such as the IFU and professional educations lines?

A Yes, it does.

Q Does that include documents from Ethicon pertaining to the design of the Prolift?

A Yes, it does.

Q You were asked about if you did an analysis. Did you do an analysis of the medical literature with regard to Prolift to formulate your opinions?

A Yes, I did.

Q Can you tell us in general how you went about doing that analysis?

A So that analysis has been ongoing since I was introduced to transvaginal repairs. And so in addition to the literature reviewed for today's deposition and for the report, the foundation for my opinion and expert report is based on my experience, my clinical experience, my

communications with other colleagues, and my review of the literature over the years as well as specific review of the literature for preparations for the report.

Q And there's been questions about Gynemesh PS and Prolift. Does Prolift use Gynemesh PS?

A Yes.

Q Do you view outcomes and studies on those two devices as being relevant and similar?

A I do. Yes.

Q Is that the way you considered those devices back when you were using and teaching them before becoming an expert?

A Correct. So we know that Gynemesh PS is the same mesh that's used in Prolift. The difference is in the design, in the cut of the mesh.

Q And would Gynemesh PS and your personal use of it, did you need to cut that mesh and trim it before using it as well?

A I have on occasion, yes. It came in sheets, so we cut it all the time when we used it for abdominal sacrocolpopexy.